Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Investigation of complications and results of clavicle fracture treatment using anterior plate or superior plate in patients referred to medical training centers of Isfahan University of Medical Sciences.

Protocol summary

Study aim
Determining and comparing the short and medium term effects of anterior and superior plate insertion in clavicle fracture

Design
The 52 patients from among the patients who met the inclusion criteria and did not meet the exclusion criteria and were admitted to medical training centers of the University of Medical Sciences were included in the study. Then they will be randomly assigned to each anterior plaque or superior plaque treatment group with the help of randomization software

Settings and conduct
Patients will surgery based on their grouping, which is done on a one-to-one basis and they are not aware of it. During the operation, 2 weeks, 1 month, 3 m and 6 m after the operation, they will go to the orthopedic clinic

Participants/Inclusion and exclusion criteria
Inclusion criteria: Clavicle fx 18 to 60 years Consent to participate study Non-entry criteria: multiple fx Open clavicle fx underlying disease such as malignancy and Pathological fx Previous clavicle fx synchronic vascular and nerve damage

Intervention groups
Patients are divided into 2 groups superior or anterior plate surgery, both methods were used in clavicle fx stabilization, but there is a debate about their superiority.

Main outcome variables
time of surgery Hospitalization period Shoulder ROM Examination of the sensation and movement of the fingers Union pain score infection The level of patient satisfaction with the position of the plaque based on the level of palpation under the skin Vascular and nerve damage during surgery Average time to return to daily life activities Cases requiring further surgery Delay Union

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230924059500N1**
Registration date: **2024-01-06, 1402/10/16**
Registration timing: **registered_while_recruiting**

Last update: **2024-01-06, 1402/10/16**
Update count: **0**

Registration date
2024-01-06, 1402/10/16

Registrant information

Name
Himan Hosseini

Name of organization / entity

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Iran (Islamic Republic of)

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+98 31 3675 4213

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-12-26, 1402/10/05

Expected recruitment end date
2024-01-15, 1402/10/25

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigation of complications and results of clavicle fracture treatment using anterior plate or superior plate in patients referred to medical training centers of Isfahan University of Medical Sciences.

Public title
Investigating complications and results of clavicle fracture treatment using anterior plate or superior plate
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Clavicle fracture Age 18 to 60 years Consent to participate in the study
Exclusion criteria:
The presence of multiple fractures of other organs Open clavicle fracture The presence of an underlying disease such as malignancy and..Pathological fracture Previous clavicle fracture The simultaneous presence of vascular and nerve damage
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **52**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
The patient will be given a full explanation of the procedure and conditions, and consent will be obtained to participate in the study, but the patient will not be informed about the position of the operation.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical Committee of Isfahan University of Medical Sciences
Street address
Hazarjarib Street; Isfahan University of Medical Sciences
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2023-08-14, 1402/05/23
Ethics committee reference number
IR.MUI.MED.REC.1402.182

Health conditions studied

1

Description of health condition studied
Fracture of clavicle
ICD-10 code
S42.0
ICD-10 code description
Fracture of clavicle

Primary outcomes

1

Description
Postoperative pain
Timepoint
2 weeks after surgery, 1 month after, 3 months after and 6 months after surgery
Method of measurement
VAS Score

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Superior plate. these patients under go clavicle fracture surgery and reconstruction using a plate placed on the superior surface of the clavicle. all other surgical protocols and post surgical care are done using a standard care and surgery protocol for the patient.
Category
Treatment - Surgery

2

Description
Intervention group 2: Anterior plate. these patients under go clavicle fracture surgery and reconstruction using a plate placed on the antero inferior surface of the clavicle. all other surgical protocols and post surgical care are done using a standard care and surgery protocol for the patient.

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra Hospital
Full name of responsible person
Mahdi Hadian
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Sofeg St
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mozhgan Mortazavi
Street address
Hazar Jarib Street, Isfahan University of Medical Sciences and Health Services
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8174673461
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m_mortazavi@med.mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mojtaba Baniasadi
Position
Assistant Professor
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available